IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lang et al.
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Invention: Minimally Invasive Joint Implant with 3-Dimensional Geometry Matching the Articular Surfaces

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

RESPONSE

Dear Sir:

This is in response to the final Office Action dated May 24, 2011. Applicants request a three-month extension of time to file this paper, and also submit a Request for Continued Examination and required fees. Please enter and consider the following claim amendments and remarks.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 9 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Currently Amended) A femoral implant system derived from an image of a patient's joint and suitable for repairing or replacing both medial and lateral femoral condyles of [[a]] the knee joint of [[a]] the patient, comprising:

a femoral implant having medial and lateral femoral condyle portions each having a superior surface and an inferior surface, wherein the superior surface is configured to oppose at least a portion of a femur and be fixed to the portion when the implant is implanted and the inferior surface is configured to oppose and articulate with at least a portion of a tibial implant surface when the implant is implanted,

wherein at least a part of said superior surface of each femoral condyle portion of said implant ~~is derived from an image of the patient's joint and~~ has a shape or dimension that substantially match the ~~geometry and/or~~ shape or dimension of the patient's condyle, and

a surgical assistance tool having at least one surface portion that has an anatomic or near anatomic fit with a corresponding portion of an articular surface of the joint and a guide or hole anatomically aligned relative to the surface portion.

~~wherein the medial condyle portion includes a perimeter defining a width that is different than the width defined by the corresponding perimeter of the lateral condyle portion~~.

2. (Cancelled)

3. (Currently Amended) The femoral implant system of claim 1, wherein the implant has a thickness of a cartilage defect in a patient.

4-7. (Cancelled)

8. (Currently Amended) The femoral implant system of claim 1, wherein the implant is constructed of a material comprising metal or metal alloy.

9. (Currently Amended) The femoral implant system of claim 1, wherein the implant comprises one or more biologically active materials.

10. (Cancelled)

11. (Currently Amended) The femoral implant system of claim 1, wherein the implant is comprised of a metal or metal alloy and a polymer.

12. (Currently Amended) The femoral implant system of claim 1 further having a structure for attachment on at least one of the superior surface and the inferior surface selected from the group consisting of: ridges, pegs, pins, cross-members, teeth, a planar surface, and protrusions.

13. (Currently Amended) The femoral implant system of claim 12 further having a plurality of structures for attachment.

14. (Cancelled)

15. (Currently Amended) The femoral implant system of claim 1 further having a peripheral structure selected from the group consisting of ridges and lips.

16. (Currently Amended) The femoral implant system of claim 15, wherein the peripheral structure extends along an entire perimeter of the implant.

17. (Currently Amended) The femoral implant system of claim 15, wherein the peripheral structure extends along a portion of a perimeter of the implant.

18-19. (Cancelled)

20. (Currently Amended) The femoral implant system of claim 1, wherein the implant is selected from a pre-existing electronic library of implants.

21-41. (Cancelled)

42. (Currently Amended) The femoral implant system of claim 1, wherein the portion of the inferior surface is configured based at least in part on image data of the patient's subchondral bone.

43-50. (Cancelled)

51. (Currently Amended) The femoral implant system of claim 1, wherein the inferior surface has a varying curvature in a sagittal plane.

52-95. (Cancelled)

96. (Currently Amended) The femoral implant system of claim 1, wherein the implant is configured based on a library of pre-existing shapes.

97. (Currently Amended) The femoral implant system of claim 1, wherein at least a portion of the inferior surface of the implant is patient-specific.

98. (Currently Amended) The femoral implant system of claim 1, wherein ~~a portion of~~ the superior surface of the implant is configured to be placed against [[a]] one or more cut bone surfaces ~~cut~~.

99. (Currently Amended) The femoral implant system of claim 1, wherein the implant is configured from at least one patient-specific measurement.

100. (Currently Amended) The femoral implant system of claim 99, wherein the one patient-specific measurement is a width in the mediolateral direction.

101. (Currently Amended) The femoral implant system of claim 99, wherein the one patient-specific measurement is a length in the anteroposterior direction.

102. (Currently Amended) The femoral implant system of claim 99, wherein the one patient specific measurement is a curvature of the joint in the coronal plane.

103. (Currently Amended) The femoral implant system of claim 99, wherein the one patient specific measurement is a curvature of the joint in the sagittal plane.

104. (Cancelled)

105. (Currently Amended) The femoral implant system of claim 104, wherein the patient-specific measurements are width in the mediolateral direction and length in the anteroposterior direction.

106. (Currently Amended) The femoral implant system of claim 104, wherein the patient specific measurements are width in the mediolateral direction and a curvature of the joint.

107. (Currently Amended) The femoral implant system of claim 106, wherein the measurement of a curvature of the joint is in the sagittal plane.

108. (Currently Amended) The femoral implant system of claim 106, wherein the measurement of a curvature of the joint is in the coronal plane.

109 – 111. (Cancelled)

112. (Currently Amended) The femoral implant system of claim 1, wherein the implant is for a multi-compartmental knee replacement.

113. (Currently Amended) The femoral implant system of claim 1, wherein the profile of the implant can be configured to alter the load bearing ability relative to the joint.

114 – 136. (Cancelled)

137. (Currently Amended) An orthopedic implant system for use in repairing or replacing two ~~one~~ or more compartments of a patient's knee joint, comprising,

a femoral implant component having a medial femoral condyle portion and a lateral femoral condyle portion, each portion having an articular surface configured to articulate with a tibial surface and a bone-abutting surface configured to attach to a surface of the knee joint, wherein at least a portion of the articular surface of ~~each~~ a condyle portion is matched to an underlying portion of the patient's joint based at least in part on imaging data of the patient's joint; and

a surgical assistance tool having at least one surface portion that has an anatomic or near anatomic fit with a corresponding portion of an articular surface of the joint and a guide or hole anatomically aligned relative to the surface portion.~~, and wherein the medial condyle portion includes a perimeter defining a width that is different than the width defined by the corresponding perimeter of the lateral condyle portion~~.

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138. (Currently Amended) A femoral implant for use in repairing or replacing two or more compartments of a patient's knee joint, the femoral implant comprising both medial and lateral~~a~~ femoral condyle portions each having an articular surface configured to articulate with a tibial surface and a bone-abutting surface configured to attach to a surface of the knee joint, wherein

at least one parameter of the articular surface of ~~each~~ at least one condyle portion of the implant is based on a patient-specific parameter derived at least in part from imaging data of the patient's joint~~, and wherein the medial condyle portion includes a perimeter defining a width that is different than the width defined by the corresponding perimeter of the lateral condyle portion~~.

139. (Currently Amended) A femoral implant for use in repairing or replacing two-or more compartments of a patient's knee joint, the femoral implant comprising both medial and lateral femoral condyle portions each having an articular surface configured to articulate with a tibial surface and a bone-abutting surface configured to attach to a surface of the knee joint, wherein the implant is selected from an electronic library of implants based on a patient-specific parameter derived at least in part from imaging data of the patient's joint~~, and wherein the medial condyle portion includes a perimeter defining a width that is different than the width defined by the corresponding perimeter of the lateral condyle portion~~.

140. (New) The femoral implant system of claim 1, wherein at least a part of said superior surface of each femoral condyle portion of said implant has a shape and dimension that substantially match the shape and dimension of the patient's condyle

141. (New) The femoral implant system of claim 1, wherein the inferior surface has a curvature or shape that matches a curvature or shape of at least a portion of an articular surface of the patient's femur.

142. (New) The femoral implant system of claim 1, wherein the superior surface includes one or more planar portions configured to abut one or more planar cut bone surfaces of the patient's femur when the implant is implanted.

143. (New) The implant of claim 139, wherein the patient-specific parameter derived at least in part from imaging data of the patient's joint is derived from a condylar measurement.

144. (New) The implant of claim 139, wherein the patient-specific parameter derived at least in part from imaging data of the patient's joint is a condylar width.

145. (New) The implant of claim 139, wherein the patient-specific parameter derived at least in part from imaging data of the patient's joint is a condylar length.

146. (New) The implant of claim 139, wherein the patient-specific parameter derived at least in part from imaging data of the patient's joint is a condylar curvature.

147. (New) The femoral implant system of claim 1, wherein the portion of the inferior surface is configured based at least in part on image data of the patient's cartilage.

148. (New) The femoral implant system of claim 99, wherein the implant is configured by selecting an implant shape from a library of pre-existing implant shapes.

149. (New) The femoral implant system of claim 148, wherein the implant is configured by adapting the implant shape selected from the library in one or more dimensions to better fit the patient's articular anatomy .

150. (New) The femoral implant system of claim 99, wherein the implant is configured by designing the implant using CAD/CAM technology.

REMARKS

Applicants wish to thank the Examiner for her review of this application and respectfully request entry of the current amendments, which do not introduce any new matter.

35 U.S.C. § 112

Claim 111 is rejected under 35 U.S.C. § 112, second paragraph. Applicants have canceled claim 111, thereby obviating this rejection.

35 U.S.C. § 103(a)

Claims 1, 3, 8, 9, 11-13, 15-17, 20, 42, 51, 96-108, 111-113 and 137-139 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,816,855 (Saleh) in view of U.S. Patent Application Publication No. 2002/0059049 (Bradbury), as evidenced by U.S. Patent Application Publication No. 2004/0204766 (Siebel).

The Office Action states that Saleh teaches that the convex bearing surfaces of the femoral component simulate the natural shaping of the condyles. The Office Action cites Bradbury as teaching manufacturing implants based on patient-specific radiological data or information. Further, Siebel is cited to provide the motivation for a skilled artisan to design an anatomical knee prosthesis that is a reproduction of the anatomy of a healthy knee joint (paragraph 0010).

However, these references, alone or in combination, do not teach or suggest the claimed invention. For example, none of the cited references teach that the femoral implant is prepared by a process involving patient-specific measurements derived from image data of the patient's joint. The cited references, alone or in combination, do not teach or suggest a femoral implant with a superior (i.e., bone-facing) surface of each femoral condyle portion of the implant having a shape or dimension that substantially match the shape or dimension of the patient's condyle of the joint that receives the implant (i.e., the patient's diseased or damaged joint). Nor do these references teach or suggest a femoral implant with an articular surface, at least a portion or parameter of which is patient-specific, i.e., derived from image data of the patient's joint that receives the implant. Additionally, these references do not teach or suggest a system as claimed in independent claims 1 and 137, *i.e.*, a system having a surgical assistance tool with at least one surface portion that has an anatomic or near anatomic fit with a corresponding portion of an articular surface of the joint and a guide or hole anatomically aligned relative to the surface portion.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Applicants believe that the application is in condition for allowance and respectfully request that a notice of allowance be issued. The Examiner is authorized to charge any fees required for timely consideration of this application to Deposit Account No. 19-4972.

Applicants invite the Examiner to contact the undersigned by telephone, if it will help advance the application through issuance.

Respectfully submitted,

/Alexander J. Smolenski, Jr., #47,953/

Alexander J. Smolenski, Jr.
Registration No. 47,953
Attorney for Applicant

Sunstein Kann Murphy & Timbers LLP
125 Summer Street
Boston, MA 02110-1618
617-443-9292
02960/00113 1551331.1